



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

June 1, 2001

WARNING LETTER NYK 2001-81

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Roger Bowers, M.D.  
Radiation Safety Officer  
St. Elizabeth Medical Group  
Mohawk Office  
5 Ann Street  
Mohawk, New York 13407

RE: Facility ID Number 182733

Dear Dr. Bowers:

Your facility was inspected on May 17, 2001 by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- *Processor QC records were missing for at least 30 percent of the operating days in the month of February 2001 for the [REDACTED] processor*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct these violations and to prevent the recurrence of similar violations.

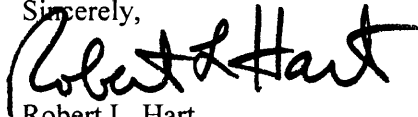
In addition, your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- *Failed to produce documents verifying the interpreting physician Raphael Alcuri met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.*
- *Failed to produce documents verifying the interpreting physician Timothy Farley met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.*

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely,



Robert L. Hart  
Acting District Director

St. Elizabeth Medical Group  
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cc: Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Program  
American College of Radiology  
1891 Preston White Drive  
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cc: Gerald O'Connor  
New York State Department of Health  
Flanigan Square  
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547 River Street  
Troy, NY 12180

cc: William Kelleher  
NYS Department of Health  
Office of Public Health  
217 South Salina Street  
Syracuse, New York 13202